K120926

JUL 27 2012

Bard Medical Division
C.R. Bard Inc.
8195 Industrial Blvd.
Covington, GA 30014

BARD | MEDICAL

Section 4: 510(k) Summary

The following information is provided as required by 21 CFR §807.92 for the EndoBeam™ Holmium Laser Fiber 510(k) premarket notification. In response to the Safe Medical Devices Act of 1990, the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

Sponsor:
BARD Medical Division
C. R. BARD, Inc.
8195 Industrial Blvd.
Covington, GA 30014

Contact:
Terri Morris
Regulatory Affairs Specialist
Bard Medical Division
C. R. Bard, Inc.
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Date Prepared: February 29, 2012

Subject Device:
Trade Name: EndoBeam™ Holmium Laser Fibers
Common/Usual Name: Holmium Laser Fiber
Classification Name: Powered Laser Surgical Instrument
Regulation: 21 CFR §878.4810
Classification: II
Product Code: GEX

Predicate Device(s): The EndoBeam™ Holmium Laser Fiber is substantially equivalent with respect to the following predicate devices:

Product	Company	510(k) Number
Laser Peripherals Holmium Bare Fibers	Laser Peripherals LLC	K972272
Laser Peripherals Reusable Holmium Fiber	Laser Peripherals LLC	K011207
SureFlex™ Laser Fiber	InnovaQuartz (a subsidiary of American Medical Systems)	K050108
SlimLineEZ™ Fiber Delivery Device	Lumenis	K011703

Device Description: The EndoBeam™ Holmium Laser Fibers are free-beam delivery devices that transmit laser energy in a forward direction. The devices are either 2.5 meters (8.2 ft.) or 3.0 meters (9.8 ft) in length and are terminated with a laser specific connector on the proximal end. These delivery systems are capable of delivering Ho:YAG (2140nm) and Nd:YAG (1064nm). The devices are either single use or reusable and are supplied Ethylene Oxide (EtO) sterilized.

The Bard Holmium series of laser fibers are fiber optic laser energy delivery devices consisting of an SMA 905 connector, strain relief, and a silica core/silica clad fiber jacketed with ethylene tetrafluoroethylene (ETFE). The fibers are further equipped with a polished, flat output tip. These fibers may be used in a variety of laser-based surgical cases as an integral part of laser systems.

The line of reusable laser fibers will feature a protective sheath outside of the jacketed fiber and extending from the strain relief to the midpoint of the fiber length.

Intended Use: The EndoBeam™ Holmium Laser Fibers are indicated for a variety of surgical uses including open, laparoscopic or endoscopic ablation, incision, excision, vaporization, and coagulation of soft and cartilaginous tissue and in surgical procedures involving vaporization, ablation, and fragmentation of calculi.

The delivery system may be used in surgical specialty or procedures for which compatible Holmium and Nd:YAG lasers have received regulatory clearance. Refer to the applicable laser system user manual for complete information regarding applications, contraindications, precautions and warnings when using this fiber.

Technological Characteristics: The EndoBeam™ Holmium Laser Fibers have the same technological characteristics as the predicate devices. The fiber core and cladding for the subject device are made from silica which is the same material used in all the predicate devices. Additionally, as with the predicate devices, the fiber coating of the subject device is constructed from hard-fluoropolymer and the fiber jacket is Ethylene Tetrafluoroethylene (ETFE). Various core diameter sizes (200, 272, 365, 365 reduced buffer, 550 and 1000 micron) are offered.

Performance Data: Nonclinical functional performance testing was conducted and included visual, functional and tensile strength testing carried out per internal test methods and per IEC 61754-22 – IEC Standard for Fiber Optic Connectors. Nonclinical biocompatibility testing in accordance with ISO 10993-1:2009, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process and FDA Bluebook Memorandum G95-1, Use of International Standard ISO 10993 "Biological Evaluation of Medical Devices Part 1: Evaluation of Testing" was conducted.

Substantial Equivalence: The EndoBeam™ Holmium Laser Fibers have the same intended use as the predicate devices. Nonclinical test data demonstrate that the device is safe and effective and is substantially equivalent to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL 27 2012

C.R. Bard, Incorporated
% Ms. Terri Morris
Regulatory Affairs Specialist, Bard Medical Division
8195 Industrial Boulevard
Covington, Georgia 30209

Re: K120926
Trade/Device Name: EndoBeam™ Holmium Laser Fibers
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: July 20, 2012
Received: July 23, 2012

Dear Ms. Morris:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Device
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 3: Indications for Use Statement

510(k) Number: K120926

Device Name: EndoBeam™ Holmium Laser Fibers

Indications for Use:

The EndoBeam™ Holmium Laser Fibers are indicated for a variety of surgical uses including open, laparoscopic or endoscopic ablation, incision, excision, vaporization, and coagulation of soft and cartilaginous tissue and in surgical procedures involving vaporization, ablation and fragmentation of calculi.

The delivery system may be used in surgical specialty or procedures for which compatible Holmium and Nd:YAG lasers have received regulatory clearance. Refer to the applicable laser system user manual for complete information regarding applications, contraindications, precautions and warnings when using this fiber.

Prescription Use: ☒ **or** **Over the Counter Use** ☐

Part 21 CFR 801 Subpart D

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mil RP Dyke for MKM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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